



ADVANCED ORTHOPAEDIC SOLUTIONS

K080408

APR 25 2008

**510(k) SUMMARY**

**SUBMITTED BY:** Advanced Orthopaedic Solutions  
2444 205<sup>TH</sup> Street, Unit 5  
Torrance, CA 90501  
(310) 533-9966  
FAX (310) 533-9876

**510(k) CONTACT PERSON:** Paul Doner, Vice President Operations

**TRADE NAME:** AOS External Fixation System

**COMMON NAME:** External Fixation

**CLASSIFICATION:** 21 CFR 888.3030 Single/multiple component  
metallic bone fixation appliances and  
accessories.

**DEVICE CODE:** KTT

**SUBSTANTIALLY  
EQUIVALENT DEVICE:** Hoffman II External Fixation System (K053472)  
Apex Fixation Pins (K011136)

**DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:**

The AOS External Fixation System is an external fixation device comprised of rods, rod-to-rod clamps, pin-to-rod clamps and threaded pins used for the management of bone fractures and reconstructive orthopedic surgery.

The AOS External Fixation System is indicated for external fixation of open or closed long bone fractures where soft tissue injury preclude the use of other fracture treatment. The AOS External Fixation System is intended to be non-weight bearing.

The system is a modular system designed to provide options in frame construction, simplicity in frame components, and ease of use. The system is comprised of titanium and stainless steel clamps (rod-to-rod and pin-to-rod), stainless steel fixation pins and carbon fiber connector rods. The AOS External Fixation system is a non-sterile single use fixation device.

The rod-to-rod clamps are designed to clamp to the 9.5mm carbon fiber rod and connect two rods together. The rod-to-pin clamps are designed to clamp to the 9.5mm carbon fiber rod and to the 5.0mm stainless steel half pins and the 5.0mm shaft on the 6.0mm center threaded pin.

The stainless steel threaded half pins are 5mm in diameter and in lengths of 180mm and 210mm. The stainless steel thread center pins have a 6.0mm thread diameter, 5.0mm shaft diameter and are 280mm in length. The 5.0mm threaded half pin and the center threaded pins have twist flutes so that they are self-drilling.

The connecting rods are carbon fiber reinforced plastic rods with an overall diameter of 9.5mm and are in length of 250mm, 300mm and 400mm.

The surgical technique used for the AOS External Fixation System is a standard method used for external fixation and is same as the technique used for the predicate devices. The instrumentation for the system consists of a wrench, a pin inserter, a drill sheath and a 4.0mm calibrated drill.

#### **SUBSTANTIAL EQUIVALENCE INFORMATION:**

Substantial equivalence for the AOS External Fixation System is based on the similarity in indication for use, design features, operating principles and material of composition to Stryker's Hoffman II Carbon Connecting Rods, K961916, Stryker's Hoffman II External Fixation System, K053472 and Stryker's Apex Fixation Pins, K011136.

The construct of the AOS External Fixation System and the predicate devices are virtually identical. Since the devices are substantially equivalent in design, geometry, construction, materials of construction and indications it was determined that no mechanical testing was necessary to demonstrate substantial equivalence.

#### **INTENDED USE:**

The AOS External Fixation System is indicated for external fixation of open or closed long bone fractures where soft tissue injury precludes the use of other fracture treatment.

The AOS External Fixation System is intended to be non-weight bearing.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Advanced Orthopaedic Solutions  
% Mr. Paul Doner  
Vice President Operations  
2444 205<sup>th</sup> Street, Unit 5  
Torrance, CA 90501

APR 25 2008

Re: K080408  
Trade/Device Name: AOS External Fixation System  
Regulation Number: 21 CFR 888.3030  
Regulation Names: Single/multiple component metallic bone fixation  
appliances and accessories  
Regulatory Class: II  
Product Code: KTT, JEC, JDW  
Dated: February 12, 2008  
Received: February 14, 2008

Dear Mr. Doner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Premarket Notification  
Indication for Use Statement

510(k) Number (if known): K080408

Device Name: AOS External Fixation System

Indications for Use:

The AOS External Fixation System is indicated for external fixation of open or closed long bone fractures where soft tissue injury precludes the use of other fracture treatment.

The AOS External Fixation System is intended to be non-weight bearing.


Prescription Use: **X**                      AND/OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use: \_\_\_\_\_  
(Part 21 CFR 801 Subpart C)

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PAGE IF NECESSARY)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K080408